

**Rejections Under 35 U.S.C. §102(b)**

The Examiner has rejected claims 1-6, 8, 10-22, 26-29, 32-36, 38, 39, 41, 42, 46-51, 53-56, 61 and 63 under 35 U.S.C. §102(b) as being anticipated by Goldberg et al (WO 01/47368, pages 4-7, 9-14, 19). (as set forth in ¶6, paper 20080213)

In making this rejection, the Examiner continues to maintain that Goldberg et al. discloses chewing gum free of non-biodegradable polymers, including two different biodegradable polymers as claimed by the Applicants, having molecular weights and glass transition temperatures within the Applicants' claimed ranges. Further, the chewing gum of Goldberg et al. also includes conventional ingredients, i.e. resins, softeners, sweeteners, flavoring agents, fillers, coloring agents and film forming agents as claimed by the Applicant and in the amounts claimed by the Applicants. The chewing gum of Goldberg et al. is also may be coated with a syrup, which results in a hard or soft coating, as claimed by the Applicants. The Applicants respectfully traverse this rejection.

As an initial matter, in reviewing the Goldberg et al. application and specifically, pages 10-14 of this application, Goldberg et al. provide a description of different types of monomers. From these monomers, various co-polymers may be manufactured by using at least two different monomers. The Examiner's contention in paragraph 9 of his final rejection that Goldberg et al. "clearly discloses the use of first and second biodegradable polymers in the gum base" is unclear and not readily understood by the Applicants. The Examiner's premise for the rejection of the pending claims under Goldberg et al. appears to be based upon a misunderstanding of the Goldberg et al. application. The Examiner appears to be of the view that a composition comprising a co-polymer of two different biodegradable monomers is the

same as a composition comprising two different biodegradable polymers. This is not true.

For a §102 rejection to be valid, the art cited must teach all limitations required by the claims that define the present invention.

As currently amended, claim 1 requires chewing gum comprising at least two different biodegradable polymers, wherein said at least two different biodegradable polymers have a different glass transition temperature  $T_g$ , wherein at least one of the biodegradable polymers has a glass transition of at least  $+1^{\circ}\text{C}$ , and wherein at least one of the at least two different biodegradable polymers has a glass transition temperature of less than  $0^{\circ}\text{C}$ .

A closer reading of Goldberg et al. shows that this application teaches a combination of biodegradable and non-biodegradable polymers. It is clear from this Final Rejection, that the Examiner has misread Goldberg et al. and that he has confused “monomers” with “polymers” on pages 10-14 of Goldberg et al. Specifically, Goldberg discloses a large number of copolymers which may be used as a chewing gum base. However, the only actual gum base disclosed in Goldberg et al. (eg. 48) comprises one biodegradable polymer and several non-biodegradable polymers. The only chewing gum disclosed in Goldberg et al. (eg. 49) comprises 26% of the above-described gum base from example 48. Thus, there is no gum disclosed in Goldberg et al. comprising at least two different biodegradable polymers. In addition, Goldberg does not disclose any effects of specific limits for the polymer glass transition temperatures.

In contrast to Goldberg et al., the chewing gum of the present invention comprises at least two different biodegradable polymers having different glass transition temperatures,  $T_g$ , wherein at least one of the biodegradable polymers has a

glass transition of at least +1°C, and wherein at least one of the at least two different biodegradable polymers has a glass transition temperature of less than 0°C (claim 1).

Since Goldberg et al. do not teach or suggest every element of the present invention as claimed, the Examiner's rejection under 35 U.S.C. §102(b) should be withdrawn.

### **Rejections Under 35 U.S.C. §103(a)**

The Examiner has rejected claims 23-25, 30, 31, 37, 40, 43, 52 and 64-66 under 35 U.S.C. §103(a) as being unpatentable over Goldberg et al. (¶7, paper no. 20080213). In making this rejection, the Examiner argues that finding the optimum amount of each component would require nothing more than routine experimentation by one reasonably skilled in the art and that the coating components are conventional chewing gum coating components. The Applicants respectfully traverse this rejection.

Goldberg et al. teaches generally the state-of-the-art assumption that biodegradable polymers must be supplemented with non-biodegradable polymers in order to achieve as successful chewing gum. Goldberg et al. primarily focuses on the amounts and types of (biodegradable and non-biodegradable) monomers which may be used in practicing the technology. Goldberg et al. does not teach or suggest the acceptable amounts of additional components which can be used in the chewing gum. In fact, Goldberg et al. only mentions the use of flavorants and does not give any range or amounts to one should use except for a single example with a defined precise amount of a flavor oil (see Example 49 in Goldberg et al.). There are no teachings or suggestions in Goldberg et al. which suggests an optimum amount of flavorants or

other components, especially in view of the fact that the single example shows the use of a flavorant at 1.800% (by weight).

In addition, one skilled in the art would not look to Goldberg et al. for limits on flavor concentration ranges since Goldberg et al. uses a mixture of biodegradable & non-biodegradable polymers. This type of chewing gum has a different moisture content and hence very different properties from the chewing gum of the present invention, which is substantially free of non-biodegradable polymers. Accordingly, there is no teaching suggestion or motivation in Goldberg et al. that would lead one skilled in the art to utilize the concentration ranges of flavorants claimed in the present invention.

The Examiner has also rejected claims 44 and 45 under 35 U.S.C. §103(a), as being unpatentable over Goldberg et al. in view of Li et al. (US 6,153,231, col. 7, lines 60-61). (¶ 8, paper no. 20080213) In making this rejection, the Examiner maintains that it would have been obvious to include a medicinal or pharmaceutical ingredient as an active ingredient in the gum of Goldberg et al., since such an ingredient is a conventional chewing gum component, as evidenced by Li et al. The Applicants respectfully traverse this rejection.

The addition of active ingredients to a gum can dramatically alter the textural properties of that gum, as these ingredients may be, for instance, acidic, basic, a salt, hydrophobic, hydrophilic, or hydrated. Hence, unless the gum bases are identical, there is no way to predict whether or not a chewing gum with added active ingredients will have the desired textural properties for the consumer. Thus, one skilled in the art would understand that there is no teaching, suggestion or motivation in Goldberg et al. for the addition of other substances (besides flavorants) to the chewing gum.

Goldberg et al. is directed to and discloses a chewing gum comprising both biodegradable and non-biodegradable polymers, the use of flavorants for such a gum, and how one skilled in the art may vary the monomers which comprise the chewing gum to achieve the desired textural properties of the gum. Thus, there is no teaching suggestion or motivation in Goldberg et al. in view of Li et al. that would lead one skilled in the art to include active ingredients in the present invention.

The Examiner has rejected claims 54-62 under 35 U.S.C. §103(a), as being unpatentable over Goldberg et al. in view of Meyers (US 5,433,960, cols. 3 & 9-13 and claims 1, 16 and 27) or Li et al. (¶ 9, paper no. 20080213). In making this rejection, the Examiner argues that it would have been obvious to coat the chewing gum in Goldberg et al. with a coating as claimed by the Applicants in order to provide storage stability, as evidenced by Meyers. The Applicants respectfully traverse this rejection.

Goldberg et al. very generally describes a coated gum product (page 9, paragraphs 1 and 2). The gum material of Goldberg et al. is a combination of both degradable and non-biodegradable polymers. The gum material of the present invention is substantially free of non-biodegradable polymers, and the polymers used are within a defined molecular weight range. It is well known to those skilled in the art that the characteristics of a chewing gum made from a mixture of biodegradable and non-biodegradable polymers is substantially different from the characteristics of a chewing gum that is made of biodegradable polymers and is substantially free on non-biodegradable polymers.

Hence, the fact that the chewing gum of Goldberg et al. *might* be coated (note that there is only a general reference to coating a gum tablet in Goldberg et al. with no accompanying examples) would not lead one skilled in the art to coat a chewing gum

that is made of biodegradable polymers and is substantially free on non-biodegradable polymers.

It is well known to those skilled in the art that the amount of water contained in a biodegradable chewing gum is critical - too much or too little moisture can have a detrimental impact on the consumer's perceived textural quality of the gum product. There is no teaching, suggestion or motivation in Goldberg et al., in view of either secondary reference that would lead one skilled in the art to conclude that chewing gum that is made of biodegradable polymers which are substantially free from non-biodegradable polymers could be successfully coated.

Consequently, in view of the above arguments, the rejections under 35 U.S.C. §103(a), have been overcome and should be withdrawn.

#### **Double Patenting Rejection**


Claims 1-6, 8, 10-13, and 15-66 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims: 1-62 of co-pending application 10/472,122; claims 1-54 of co-pending application 10/472,154; claims 1-7 and 10-57 of co-pending application 10/528,927; claims 1-64 of co-pending application 10/529,130; claims 1-20, 22-26, and 28-42 of co-pending application 10/529,133; claims 1-55 of co-pending application 10/529,137; and claims 1, 2, 10, 11, 13-18, 24-26 and 28-54 of co-pending application 11/088,109.

Upon indication of allowable subject matter in this case, Applicants will file the appropriate terminal disclaimers in order to overcome these rejections.

The present application as amended herein, is now in form for allowance and early reconsideration and allowance of the claims, as currently pending, is earnestly solicited.

Respectfully submitted,

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I hereby certify that this correspondence is being electronically filed with The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, this 29th day of January 2009.

  
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